

## **REMARKS**

### **I. Introduction**

By the present Amendment, claims 1, 21, 23, and 24 have been amended. No claims have been added or cancelled. Accordingly, claims 1, 3, 6, and 8-24 remain pending in the application. Claims 1, 21, 23, and 24 are independent.

### **II. Office Action Summary**

In the Office Action of October 19, 2009, the Abstract was objected to because of an informality. Claims 1, 3, 6-9, 12, 13, 18, 20-22, and 24 were rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 6,132,373 issued to Ito et al. ("Ito '373"). Claims 10, 11, 15-17, 19, and 23 were rejected under 35 USC §103(a) as being unpatentable over Ito '373 in view of U.S. Patent No. 5,353,220 issued to Ito et al. ("Ito '220"). Claim 14 was rejected under 35 USC §103(a) as being unpatentable over Ito '373 in view of U.S. Patent No. 5,615,680 issued to Sano. These rejections are respectfully traversed.

### **III. Objections to the Abstract**

The Abstract of the Disclosure was objected to because of an informality. Regarding this objection, the Office Action indicates that the Abstract contains two (2) paragraphs.

Applicants disagree with this assertion. The Abstract was previously amended to be in the form of a single paragraph. However, deletion of the paragraph break was not readily noticed because this was a formatting change. Nonetheless, Applicants have amended the Abstract to clearly show that it contains

a single paragraph. Additionally, several reference labels that were inadvertently retained have not been deleted.

Withdrawal of this objection is therefore respectfully requested.

**IV. Rejections under 35 USC §102**

Claims 1, 3, 6-9, 12, 13, 18, 20-22, and 24 were rejected under 35 USC §102(b) as being anticipated by Ito '373. Regarding this rejection, the Office Action alleges that Ito '373 discloses an apparatus for measuring an intima-media thickness of a blood vessels which includes a data analyzing device for receiving image data and calculating the intima-media thickness, digital data which includes a plurality of luminance values each corresponding to respective ones of a plurality of pixels, a data analyzing device that includes a setting device for setting a base position between a center of the blood vessel and a position in the vicinity of an inner intima wall, a calculation device for detecting maximum value and a minimum value from the among the luminance values corresponding to a predetermined number of pixels, and calculating the intima-media thickness based on the maximum and minimum values. The Office Action further alleges that Ito discloses that a certain part of the image of the blood vessel, including parts of the intima-media, is extracted as a target part which is a line of pixels extending along the radius of the blood vessel. The Office Action goes on to assert that the setting device calculates a moving average of the luminance values in the target part and sets a base position between the center of the blood vessel and the position in the vicinity of the inner intima wall of the blood vessel within the target part of the image. A thickness calculation device that includes 1-5 detection devices is indicated as being provided for detecting maximum and minimum values of luminance. Ito '373 is also indicated as adopting a

composite thickness of the tunica intima and media thickness of a carotid artery as an index of judgment of arterial sclerosis. Applicants respectfully disagree.

As amended, independent claim 1 defines a medical imaging diagnostic apparatus that obtains image data from a blood vessel of an object being examined and measures the composite thickness of a tunica intima and tunica media of the blood vessel. The medical imaging diagnostic apparatus comprises:

extraction means for extracting the tunica intima and the tunica externa of the blood vessel based on the brightness value of the image data;

controlling means for measuring a composite thickness of the tunica intima and the tunica media of the blood vessel on a region of the tunica intima and a region of the tunica externa, and

setting means for setting reference points of the tunica intima or the tunica externa of the blood vessel based on the brightness value of the respective regions and for setting a threshold of a subtraction of the extracted brightness value of the image data from the brightness value of the reference points,

wherein in the composite thickness of the tunica intima and the tunica media of the blood vessel is measured based on their reference points and the threshold.

The medical imaging diagnostic apparatus of independent claim 1 includes extraction means for extracting the tunica intima and the tunica externa of the blood vessel based on the brightness value of the image data, and controlling means for measuring a composite thickness of the tunica intima and the tunic media of the blood vessel based on a region of the tunica intima and a region of the tunica externa. A setting means is provided for setting reference points of the tunica intima or the tunica externa of the blood vessel based on the brightness value of the respective regions and for setting a threshold of a subtraction of the extracted brightness value of the image data from the brightness value of the reference points.

Furthermore, the composite thickness of the tunica intima and the tunica-media of the blood vessel is measured based on their reference points and the threshold.

Ito '373 discloses an apparatus for measuring the thickness of the intima-media of a blood vessel. An ultrasound device is provided for outputting digital image data which represents an image of the blood vessel based on scanning with an ultrasound, and a data analyzing device which receives the output digital image data and calculates the intima-media thickness of the blood vessel based on the digital image data. A plurality of luminance values which correspond to respective pixels of the image are included in the digital image data. Maximum and minimum values are detected from among the luminance values, and the intima-media thickness is calculated based on the maximum value and the minimum value. According to Ito '373, the IMT measurement only uses reference points based on the brightness value.

In contrast, the present invention provides IMT measurement wherein both reference points and a threshold value. The threshold value is based on subtraction of extracted brightness values of the image data obtained by the extraction means and the brightness value of the reference points. Accordingly, it is possible for the medical imaging device of independent claim 1 to perform accurate IMT measurement regardless of individual variations of the object because the brightness range is set with respect to each object. Ito '373 fails to provide any disclosure or suggestion for features now recited in independent claim 1, such as:

controlling means for measuring a composite thickness of the tunica intima and the tunica media of the blood vessel on a region of the tunica intima and a region of the tunica externa, and

setting means for setting reference points of the tunica intima or the tunica externa of the blood vessel based on the brightness value of the respective regions and for setting a threshold of a subtraction of the

extracted brightness value of the image data from the brightness value of the reference points,

wherein in the composite thickness of the tunica intima and the tunica media of the blood vessel is measured based on their reference points and the threshold.

It is therefore respectfully submitted that independent claim 1 is allowable over the art of record.

Claims 3, 6, and 8-20 depend from independent claim 1, and are therefore believed allowable for at least the reasons set forth above with respect to independent claim 1. In addition, these claims each introduce novel elements that independently render them patentable over the art of record.

Independent claim 21 defines a medical imaging diagnostic apparatus that obtains image data from a blood vessel of an object being examined. The apparatus comprises:

extraction means for extracting the tunica intima and the tunica externa of the blood vessel based on the brightness distribution in the thickness direction of the blood vessel in the image data;

controlling means for measuring a composite thickness of the tunica intima and the tunica media of the blood vessel on a region of the tunica intima and a region of the tunica externa, and

setting means for setting reference points of the tunica intima or the tunica externa of the blood vessel based on the brightness distribution of the respective regions and for setting a threshold of a subtraction of the extracted brightness distribution of the image data from the brightness distribution of the reference points,

wherein in the composite thickness of the tunica intima and the tunica media of the blood vessel is measured based on their reference points and the threshold.

According to some of the features of independent claim 21, the extracting means extracts the tunica intima and the tunica externa of the blood vessel based on the brightness distribution in the thickness direction of the blood vessel in the image

data, and the controlling means measures a composite thickness of the tunica intima and the tunica media of the blood vessel on a region of the tunica intima and a region of the tunica externa. The setting means sets reference points of the tunica intima or the tunica externa of the blood vessel based on the brightness distribution of the respective regions and for setting a threshold of a subtraction of the extracted brightness distribution of the image data from the brightness distribution of the reference points. These features do not appear to be disclosed or suggested by Ito '373.

It is therefore respectfully submitted that independent claim 21 is allowable over the art of record.

Claim 22 depends from independent claim 21, and is therefore believed allowable for at least the reasons set forth above with respect to independent claim 21. In addition, this claim introduces novel elements that independently render it patentable over the art of record.

Independent claim 24 defines a medical imaging diagnostic method that includes:

- extracting the tunica intima and the tunica externa of the blood vessel based on the brightness value of the image data;

- measuring a composite thickness of the tunica intima and the tunica media of the blood vessel on a region of the tunica intima and a region of the tunica externa, and

- setting reference points of the tunica intima or the tunica externa of the blood vessel based on the brightness value of the respective regions and for setting a threshold of a subtraction of the extracted brightness value of the image data from the brightness value of the reference points,

- wherein in the composite thickness of the tunica intima and the tunica media of the blood vessel is measured based on their reference points and the threshold.

The medical imaging diagnostic method of independent claim 24 recites various steps that correspond to operation of the elements recited in independent claim 1. As previously discussed, Ito '373 fails to provide any disclosure or suggestion for such features.

It is therefore respectfully submitted that independent claim 24 is allowable over the art of record.

**V. Rejections under 35 USC §103**

Claims 10-11, 15-17, 19, and 23 were rejected under 35 USC §103(a) as being unpatentable over Ito '373 in view of Ito '220. Claim 14 was rejected under 35 USC §103(a) as being unpatentable over Ito '373 in view of Sano. Regarding this rejection, the Office Action alleges that Ito '373 discloses all the features recited in, for example, independent claim 23. The Office Action admits that Ito '373 fails to disclose a binarization process and obtaining tunica intima based on color distribution, and reconstructing images and three dimensional image data. Ito '220 is relied upon for disclosing a three dimensional image data which uses Doppler image data, extracting positions of blood vessels after binarization by threshold processing for each data in their respective colors, and displaying a 3D color Doppler image by respective color reconstructed. Applicants respectfully disagree.

Independent claim 23 defines a medical imaging diagnostic apparatus that comprises:

imaging means for obtaining image data related to a blood vessel of an object being examined;

Doppler imaging means for obtaining color Doppler image data related to the blood vessel;



brightness distribution acquisition means for acquiring the brightness distribution in the thickness direction of the blood vessel wall of the color Doppler image data;

setting means for setting the local maximal point, out of the local maximal points appearing in the brightness distribution, having the maximum brightness as the tunica externa reference point;

extraction means for extracting the pixels, in relation to the respective pixels within the setting range including the tunica externa reference point, wherein the brightness belongs to the setting range; and

calculating means for calculating the distance between the boundary of the lumen and the tunica intima being obtained based on the color information and the boundary in the lumen side of the region formed by the pixels being extracted based on the tunica externa reference point.

The medical imaging diagnostic apparatus of independent claim 23 includes an imaging means for obtaining image data related to a blood vessel of an object being examined, Doppler imaging means for obtaining color Doppler image data related to the blood vessel, and a brightness distribution acquisition means for acquiring the brightness distribution in the thickness direction of the blood vessel wall of the color Doppler image data. A setting means is provided for setting the local maximal point out of the local maximal points appearing in the brightness distribution, having the maximum brightness as the tunica externa reference point. An extraction means is provided for extracting the pixels in relation to the respective pixels within the setting range, including the tunica externa reference point. A calculating means is provided for calculating the distance between the boundary of the lumen and the tunica intima obtained based on the color information and the boundary in the lumen side of the region formed by the pixels being extracted based on the tunica externa reference point.



Contrary to the assertions made in the Office Action, Ito '373 fails to provide any disclosure or suggestion for setting reference points as in the present invention, and calculating any distances or thicknesses based on the reference points that have been set. Applicants' review of Ito '220 has also failed to reveal any disclosure or suggestion for such features. Ito '220 only appears to disclose construction of a three-dimensional image using a plurality of Doppler image data. The combination of Ito '373 and Ito '220 fails to disclose or suggest all the features recited in independent claim 23.

It is therefore respectfully submitted that independent claim 23 is allowable over the art of record.

**VI. Conclusion**


For the reasons stated above, it is respectfully submitted that all of the pending claims are now in condition for allowance. Therefore, the issuance of a Notice of Allowance is believed in order, and courteously solicited.

If the Examiner believes that there are any matters which can be resolved by way of either a personal or telephone interview, the Examiner is invited to contact Applicants' undersigned attorney at the number indicated below.

**AUTHORIZATION**

Applicants request any shortage or excess in fees in connection with the filing of this paper, including extension of time fees, and for which no other form of payment is offered, be charged or credited to Deposit Account No. 01-2135 (Case: 529.46525X00).

Respectfully submitted,  
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